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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/812,582

03/30/2004

Jill Embry

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Medtronic

Attn: Noreen C. Johnson, IP Legal Department

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EXAMINER

PRICE, NATHAN R

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

06/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/812,582	Applicant(s) EMBRY ET AL.	
	Examiner NATHAN R. PRICE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. This office action is responsive to the amendment filed on February 12, 2009. As directed by the amendment: claims 1, 10, 13, 14, 27, 28, 30, and 34 have been amended, claim 9 has been cancelled, and no new claims have been added. Thus, claims 1-8 and 10-37 are presently pending in this application.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 14, 15, and 17-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffeen et al. (US 20030012080). Coffeen et al. discloses a surgical system and method for delivery of a viscous fluid (see fig. 20a-b) comprising: a reservoir member 40 (fig. 20b) for storing a viscous fluid, the reservoir member having an orifice 46 (fig. 20b) defined in an end thereof, a plunger member 64 (mislabeled as 46 in fig. 20b; see par. 0066) sized and shaped to engage the reservoir member in a threaded engagement (engagement between threads of element 68 and threads of element 40 in fig. 20b), and a mixer assembly including a mixer shaft (threaded rod disposed within element 120 distal of element 88; fig. 20b) and a mixer head 128 (fig. 20b), the mixer shaft extending through the plunger member (extends through element 120 at center of plunger member, see fig. 20b), the mixer assembly being rotatable to

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mix the viscous fluid through the orifice of the reservoir member (see fig. 20b, mixer assembly capable of being rotated); an opening formed in an end of the reservoir member (open proximal end of reservoir 40, fig. 20b) opposing the orifice end, the opening being adapted to receive the plunger member (see fig. 20b); the plunger is generally T-like in shape (see fig. 20b; inner member of the plunger extends distally and then bends at 90 degrees to extend laterally to form a T-like shape); the mixer assembly comprises a mixer (see above) and a mixer handle 132 (fig. 20b) connectable with the mixer; the mixer includes a receptacle defined therein for receiving a corresponding post extending from the mixer handle (see proximal end of mixer rod which receives a post from element 88, fig. 20b); the mixer is adapted to be inserted into a first end of the plunger member and the mixer handle is adapted to be inserted into a second end of the plunger member (both the mixer and the mixer handle are shaped in such a way as to be capable of being inserted into the respective ends of the plunger member; see fig. 20b), the second end opposing the first end; the mixer head having a plurality of mixer blades, each comprising a slot 134 defined therethrough (fig. 20b); a bore defined through the plunger member (bore within element 120, fig. 20b) defining an annular surface of the plunger member which is threaded along a portion thereof (see fig. 2b); the mixer includes a threaded surface for engaging with the threaded portion of the inner annular surface of plunger member (exterior surface of mixer member is threaded; see fig. 20b); and an undulating surface on a portion of the reservoir member (see fig. 20a, undulations on element 44).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 5-8, 10, 11, 28, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (US 20040204715) in view of Vetter (US 4874381). Evans et al. discloses a delivery system and method (see claim 28) made up of a housing 200 which is divided into a handle 220 and a coupling member 210; a plunger member 100 made up of a threaded section 114 and a knob 120; a reservoir 300; the threaded portion is adapted to engage with the coupling portion (par. 0043); tubing 310 and an orifice (par. 0046) through the distal end of the reservoir 300; a handle 220 which undulates; a threaded flange to engage with the threaded portion of the reservoir (par. 0047), except for the plunger head selectively attachable to and rotatable with respect to a distal end of the plunger member. However, Vetter teaches a plunger head selectively attached to and rotatable with respect to a distal end of a plunger member (col. 3, ln. 58-68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Evans et al. apparatus and method such that it comprises the plunger head selectively attachable to and rotatable with respect to a distal end of the plunger member, as taught by Vetter, for the purpose of providing an improve seal between the plunger member and the wall of the

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reservoir and preventing rotation of one member from translating to rotation of the other member (col. 3, ln. 58-68).

5. Claims 3-4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. in view of Condon (US 5307841). Evans et al. discloses the apparatus as claimed, including a knob at the proximal end of the disclosed device. However, the knob is flat. Condon discloses a knob 18 which is hemispherical in shape with an undulating cross section, the hemispherical portion being a uniform compression surface. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the knob of Evans et al. with the knob of Condon to allow the user to push the knob while simultaneously rotating the knob.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. Evans et al. discloses a handle extending from the coupling portion formed to fit the user's hand. Applicant has recited the claimed obtuse angle as a preferred embodiment, and has failed to establish any criticality with respect to the specified angle range. Absent criticality or unexpected results, one of ordinary skill in the art at the time the invention was made would have been inclined to select various angle sizes for the angle between the handle and coupling portion including the claimed range.

7. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coffeen et al. in view of Solomon (US 4277184). Coffeen et al. discloses the apparatus as claimed except for a funnel for aiding in the loading of the reservoir. However, Solomon discloses a funnel 18 to be placed in the proximal end of the reservoir to provide easier loading of the reservoir. Both the device of Coffeen et al. and of Solomon are used for

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mixing a viscous material before delivering it from the reservoir in which it was mixed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Coffeen et al. apparatus such that it comprises a funnel, as taught by Solomon, for the purpose of improving the ease with which the reservoir is loaded.

8. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. in view of Vetter, and further in view of Condon. Evans et al. discloses the apparatus as claimed, except that the knob of Evans et al. is flat. Condon teaches a knob 18 which is hemispherical in shape with an undulating cross section, the hemispherical portion being a uniform compression surface. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Evans et al. in view of Vetter apparatus such that the knob is hemispherical in shape with an undulating cross section, the hemispherical portion being a uniform compression surface, as taught by Condon, for the purpose of allowing the user to push the knob while simultaneously rotating the knob.

Response to Arguments

9. Applicant argues in the Remarks that the newly added limitations are patentable over the prior art applied in the previous action. Those new limitations have been addressed in the rejections above. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **NATHAN R. PRICE** whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art
Unit 3763